



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0981]

Withdrawal of Approval of New Animal Drug Applications; Butorphanol; Doxapram;  
Triamcinolone; Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) and three abbreviated new animal drug applications (ANADAs) at the sponsors' request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: The following sponsors have requested that FDA withdraw approval of the NADA and ANADAs listed in table 1 of this document because the products are no longer manufactured or marketed.

Table 1--NADA and ANADAs for Which Withdrawal of Approval Has Been Requested

NADA/ ANADA Number	Trade Name (drug)	Applicant
100-556	Vigorena Feeds Hy-Ty Premix (tylosin phosphate)	Springfield Milling Corp., Vigorena Feeds, Springfield, MN 56087
200-435	RESPIRAM (doxapram hydrochloride) Injection	Modern Veterinary Therapeutics, LLC 18001 Old Cutler Rd., suite 317, Miami, FL 33157
200-446	BUTORPHINE (butorphanol tartrate) Injection	Modern Veterinary Therapeutics, LLC 18001 Old Cutler Rd., suite 317, Miami, FL 33157
200-459	VETAZINE (triamcinolone) Cream	Modern Veterinary Therapeutics, LLC 18001 Old Cutler Rd., suite 317, Miami, FL 33157

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given that approval of NADA 100-556 and ANADAs 200-435, 200-446, and 200-459, and all supplements and amendments thereto, is hereby withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: September 27, 2012.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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